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October 6, 2003

8EHQ-03-15445

Document Processing Center
EPA East (Mail Code 7407M)
Attn: TSCA Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20460-0001

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Dear Madam or Sir:

Enclosed are summaries of 43 toxicology studies conducted by or for Degussa AG in Germany. These summaries reflect the results of one or more studies conducted on each of 21 chemical substances. Twelve of the summaries include information which we are reporting pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). The remaining nine studies include information that suggests that the test substance may cause adverse health or environmental effects at high exposure levels. However, because these substances are manufactured or imported in the United States only in limited quantities for use as intermediates in chemical synthesis, they do not currently present a substantial risk to health or the environment. We are therefore submitting them to EPA on a "For Your Information" basis.

These 21 summaries are being submitted pursuant to a data review that Degussa is conducting in connection with its implementation of a new computer system that will permit Degussa Corporation in the United States to access data previously available only to Degussa AG in Germany. Recognizing that a large number of these studies might need to be reported under TSCA 8(e), Degussa proactively contacted EPA in mid 2002 and proposed to review the studies in batches and submit any 8(e) reportable data to EPA within 15 business days (now 30 calendar days) of completing its review of each batch. Degussa estimated that the review would take approximately six month to complete. In a memorandum received in November 2002, the Agency concurred in this approach.

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These studies were made available to Degussa Corporation in April 2003. Degussa's toxicologists in Germany have reviewed more than 750 studies on approximately 100 chemical substances and prepared English summaries of the results of 70 studies for evaluation by scientists in the United States for reporting under TSCA Section 8(e). This submission represents Degussa's review of this first batch of studies by our scientists in Germany and the United States, which was completed on September 12, 2003. Degussa has determined that approximately 1500 studies remain to be reviewed. As we have separately informed Ms. Ann Pontius of the Toxics and Pesticides Enforcement Division, we estimate that the review of the remaining studies will take an additional nine months to complete. We will continue to submit reportable and FYI studies to EPA as our review of subsequent batches is completed.

We appreciate your attention to this matter and request your comments regarding the approach we have taken. Please do not hesitate to call me at (973) 541-8047 if you have any questions or wish to discuss this matter further.

Best regards,

Shaun F. Clancy, Ph.D.

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Degussa Corporation

Memo

To: File

From: Shaun Clancy

CC:

Date: 10/06/03

Re: TSCA 8(e) Review – 61260-55-7

Two endpoints were provided by Fine Chemicals for 61260-55-7 (HMBTAD)

- Acute Oral Tox
- Skin Irritation
- Eye Irritation

This chemical is used as an intermediate in organic synthesis and is not expected to be used in a way such that human exposure outside of an industrial setting will occur or that an environmental exposure will result. Appropriate Personal Protective Equipment is specified in the MSDS as is warnings not to allow the substance to be released. When used correctly the risk for human and environmental exposure is minimal.

There were signs of possible neurotoxicity and there were target organ effects observed in a number of abdominal organs. Given the high dose, other toxic effects and the reversibility of the possible neurotoxic effects, it is not clear that the potential neurotox effects are due to neurotoxicity. It is concluded that these effects may be considered to be reportable under TSCA 8(e) and will be submitted.

The results of the skin and eye irritation studies are not surprising given that the chemical is an amine. These results will not be reported.

ains No CBI

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Fax

To: Shaun Clancy
S-SR-US-EHS

Fax-No. Recipient: 001-973 541 8040

Pages (total): 13

cc: Dr. W. Mayr/FC-TME-CSM

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Fine chemicals
Chemicals Safety
Management

FC-TME-CSM/Dr.Jbi/sch

August, 6 2003

Initial notice of Information for possible TSCA 8e submission
N,N,-Bis(2,2,6,6-tetramethyl-4-piperidinyl-1,6-hexanediamine, HMBTAD, CAS-No. 2855-27-8

Dear Shaun,

Please find attached data obtained for the above mentioned substance for assessment of possible TSCA reportability.

I am at your disposal for any further questions.

English translations of the summaries and/or results of the studies are attached.

Best regards

Sylvia Jacobi

degussa.

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Fine chemicals
Chemicals Safety
Management

August 6, 2003

Initial Notice of Information to be assessed for Possible TSCA, Sec. 8e Reporting

Name / Trade name of the Substance	**N,N-Bis(2,2,6,6-tetramethyl-4-piperidinyl)-1,6-hexanediamine / HMBTAD**
CAS-No.:	61260-55-7

Human Health Effects [x]

Environmental Effects [ ]

Degussa-Study-No.:	85-0262-DKT 85-0264-DKT 85-0266-DKT
Other Source of information:	

Summary of Adverse Effects
Acute oral toxicity study in rats
Source Degussa AG, unpublished report No. 85-0262-DKT
Guideline OECD 401, non-GLP

Doses of 501, 631, 794, and 1000 mg/kg bw were administered as solution in corn oil (Volume 10 ml/kg bw) to groups of 5 male and 5 female Wistar rats.

The LD50 was 820 mg/kg bw. Symptoms indicative of possible neurotoxicity included prone position, staggered gait, twitching, mild to strong sedation, ataxia, tremor, crouched posture and hypothermia. At the highest dose in some cases paralysis of the hind limbs was observed, which was probably a pre-mortal finding. Symptoms disappeared in the surviving animals within 48 hours.

Hyperemia of the gastric mucosa, liver enlargement and dark coloration of the liver were observed in animals that died during the study. Animals that were sacrificed at the end of the observation period showed in some cases hyperemia of the mucosa of the stomach and small intestine, spotted kidneys (4 animals).

Acute skin irritation study in rabbits
Source: Degussa AG, unpublished report No. 85-0264-DKT
Guideline: OECD No. 404 (1981), non-GLP.

0.5 g of the test substance was applied to the shaved back of six rabbits (3m, 3f) for 4 h under occlusive conditions. Erythema grade 4 and Edema

degussa.

grade 3.83 was observed. Necrosis and was observed from 1 h after removal of the patch and did not resolve within 72 h. In 4 test animals destruction of the deeper skin layers was observed. At day 72 eschar formation was observed in all animals. The test substance caused severe irritation/corrosion of the skin within the exposure period. After an exposure time of 3 minutes necrosis did not occur.

Acute eye irritation study in rabbits
Source: Degussa AG, unpublished report No. 85-0266-DKT
Guideline: OECD No. 405 (1981), non-GLP
The study was performed with one animal. 100 mg of the solid test substance was applied to the conjunctival sac of one eye. The eye was not rinsed. After one hour severe corrosion was observed, corneal opacity and green coloration as well as corrosion of the conjunctivae and nictating membranes were observed. Due to the severe effects the study was terminated after 1 hour.

According to the pH of a saturated solution in water was 10 at 20 °C. Therefore a corrosive effect of the pure substance can be expected from the pH.

Nature and Extent of Risk Involved:
Risk of incapacitation due to severe irritation and corrosion to skin and eyes.
Possible neurotoxic effects after oral ingestion.

Information by	Date:
Dr. Sylvia Jacobi	August 6, 2003

Chemische Werke Hüls
- Toxicology -

Marl, 1/17/1985

Report No. 0351

Test of the Acute Irritant Action of HMBTAD on the Eyes and Conjunctivae

by

P. Mürmann

I Summary:

HMBTAD was applied undiluted in the eyes and conjunctival sacs of male and female rabbits.

Result:

HMBTAD had a highly irritant action on the eye and conjunctiva of one male rabbit.

The evaluation according to Appendix VI of the Council Directive 79/831/EEC (amending for the sixth time Directive 67/548/EEC) after 24, 48 and 72 hours to find the mean values of the effects on cornea, iris and conjunctiva could not be conducted because of the severe irritant action. Because of the severe caustic action of HMBTAD, only one animal was used and the test was interrupted after only 1 hr.

V Results:

The reaction findings for cornea, iris and conjunctiva are shown in the following Tables 1–3. Because of the very prompt caustic action, HMBTAD must be considered highly irritant to the eye and conjunctiva.

Author and Study Director

[Signature]
(Dr. P. Mürmann)
Veterinary Specialist in Pharmacology and Toxicology

T R A N S L A T I O N

Chemische Werke Hüls
- Toxicology -

Marl, 26.01.1985

Report No. 0350

Test of the acute irritation of the skin by

HMBTAD

by

P. Mürmann

Summary:

To test the acute irritation of the skin,

HMBTAD

was tested on the shorn dorsal skin of rabbits. The product was applied undiluted, and the exposure time in the patch test was 4 hours.

Result:

On the skin of male and female rabbits, HMBTAD displayed a strongly irritant effect (irritation index 7.71/8). Necrosis occurred after 4 hours, but not after 3 minutes.

V Result:

The following table contains the results of the test.

Numerical evaluation of the reactions, individual values and means.

Animal No.	Ear mark	Sex	1 hour		24 hours		48 hours		72 hours	
			E	OE	E	OE	E	OE	E	OE
1	92405	male	x4	4	x4	4	*+-4	4	Es-x4	4
2	93121	male	x4	2	x4	4	*+-x4	4	Es x4	4
3	93151	male	x4	3	x4	4	x4	4	Es x4	4
4	92690	female	*x4	4	x4	4	+-x4	4	Es-x4	4
5	93866	female	*x4	3	x4	2	-+x4	4	Es-x4	4
6	93870	female	x4	4	x4	4	x4	4	Es x4	3
$\bar{x}$ absolute			7.33		7.67		8.00		7.83	

30.83 : 4 = 7.71 = irritation index

E = erythema
OE = oedema
x = necrosis with bleeding and severe green discoloration
* = necrosis, green discoloration at the edge of the application area
+ = induration of the necrotic application area
- = wounds in depth
Es = eschar

The irritation index was thus 7.71/8 and thus a single dermal application of 0.5 g of HMBTAD had a strongly irritant effect for male and female rabbits.

Evaluation in accordance with Appendix VI of the 6th Amendment (79/831/EEC):

Erythema: $\bar{x}$ = 4.00

Oedema: $\bar{x}$ = 3.83

However, after an exposure time of 3 minutes, necrosis did not occur.

Author and Study Director

[signature]

(Dr. P. Mürmann)

Specialist Veterinarian for Pharmacology and Toxicology

Marl, 23.01.1985

Chemische Werke Hüls
- Toxicology -

Report No. 0349
Acute oral toxicity of

HMBTAD

for rats

by
P. Mürmann

Summary:

In a determination of the acute oral toxicity on male and female rats it was found that the LD_{50} of HMBTAD is 820 mg/kg of bodyweight. The treated animals showed symptoms of toxicity for up to 48 hours. There was no effect on increase in bodyweight. Dissection at the end of the experiment showed in some animals hyperaemia of the gastric mucosa and small intestine mucosa and occasionally fleck formation on the kidneys.

V The table below summarizes the results of the test.

HMBTAD

Acute oral toxicity (LD_{50}) for rats

Dose mg/kg	Sex	Toxicological result	Death occurred within (h)	LD_{50} mg/kg
501	male	0/5/5*		
	female	0/5/5	-	
631	male	2/5/5		
	female	0/5/5	4	
				820 (703-956) slope function S = 1.36
794	male	4/5/5		
	female	2/5/5	24	
1000	male	3/5/5		
	female	3/5/5	24	

* number of animals which died/number of animals with signs/number of animals used

Increase in bodyweight (means) in g

Dose mg/kg	Before administration (fasting)	24 h after administration	1 week after administration	2 weeks after administration
501	154.2	163.0	184.8	208.1
631	175.6	166.5	195.1	210.6
794	173.8	160.8	190.8	203.3
1000	98.8	102.5	136.3	165.8

The treatment had virtually no effect on the changes in bodyweights.

Symptoms which occurred from approximately 30 minutes after administration were ruffled fur, in some case prone position, staggering, twitching, mild to strong sedation and ataxia, dark eyes and tremor and later crouched posture, hypothermia and, at the highest dose, in some cases paralysis of the rear legs. After 48 hours, all animals were free from symptoms.

In the post-mortem dissections, hyperaemia of the gastric mucosa and small intestine mucosa, stasis liver and dark-coloured liver were observed. Dissection at the end of the test revealed in some animals hyperaemia of the gastric mucosa and small intestine mucosa, spots on both kidneys in 2 animals and in 2 animals only on the right kidney.

Author and Study Director
[signature]
(Dr. P. Mürmann)
Specialist Veterinarian for Pharmacology and Toxicology